REMARKS

The Office Action mailed September 4, 2008, and the prior art relied upon therein have been carefully studied. The claims in the application are now claims 1, 3-15, 17 and 19, and these claims define patentable subject matter under Sections 102 and 103, and therefore should be allowed. Favorable reconsideration and allowance are again respectfully requested.

Some amendments have been made in the claims above. The first feature of claim 16 has now been incorporated into claims 1 and 13. Claims 16 and 18 have been deleted, and claim 19 has been amended to avoid redundancy. Claim 13, still withdrawn, has also been amended consistent with claim 16 and also consistent with claim 4.

Applicants thank the examiner for explaining why claim 13 has remained withdrawn. Applicants do not agree with the examiner's reasoning, because claim 13, like the elected claims, call for a "light-stablized soft capsule formulation…." Applicants also do not agree that a linking claim must have a claim which depends therefrom.

Nevertheless, the examiner's reasoning having been explained, claim 13 has been amended so that it no longer depends from claim 11.

Applicants again request that claim 13 be rejoined, examined, and allowed.

Claims 1, 3-9 and 14-19 have been rejected as obvious under Section 103 from Iida in view of Bossert. The rejection is respectfully traversed, in part for the reasons of record (see prior discussion of Iida), and for the reasons set forth below.

The present invention is directed to a light-stabilized soft capsule having a reduced size (see claims 4 and 13). Such a capsule allows children, elderly people, or patients with reduced swallowing ability to swallow the capsule with ease. However, since the smaller a size of capsule, the thinner the shell thickness must be of the capsule, conventional formulations for capsule shells could not ensure a shell thickness great enough to provide light shielding of a light unstable active ingredient. Please refer to page 2, line 22, to page 3, line 6, of the present specification.

In order to provide sufficient light shielding especially for small capsules (although also useful for large

capsules), it is therefore necessary to include a non-water-soluble light-shielding agent in the capsule shells at a very high content. However, it is difficult to ensure successful dispersion of a higher amount of non-water-soluble light-shielding agent from the beginning to the end of the encapsulation process even when the non-water-soluble light-shielding agent is added to a solution of a gelling agent used for forming capsule shells. Please refer in this regard to page 25, lines 5-9, of the present specification.

Under such circumstances, the present inventors have developed a formulation for enabling the inclusion of a high content, 10 to 25 wt%, of a non-water-soluble light-shielding agent, especially useful in capsule shells having a thickness of 200μm or less on an average as claimed.

As the Examiner states in the Office Action, Iida differs from the present invention in that it does not disclose the concentration of non-water-soluble light-shielding agent of 5 to 30 wt% on the basis of the total weight of the capsule shell. Indeed, the amount of white pigment disclosed in Iida is described as only being 1.5 % by weight (or less) of the total amount of capsule shell components.

The reason why the amount of white pigment disclosed in Iida is low is because it is commonly known in the art that

the effect of a light-shielding agent is not dose-dependent and is maxed out when it is used at a relatively high content for preparing a capsule having a standard shell thickness.

This is supported by the disclosure of Iida which shows in Tables 1 and 3 that a soft capsule of Example 5 whose shell contains 1.00% by weight of titanium oxide (TABLE 1) exhibits a sufficient light-stability, which is expressed by a residual level of 97.4% (TABLE 3). Although Iida does not disclose the thickness of the capsule shells of Example 5, it is certain that the thickness falls within a range of 200μm to 600μm, since Iida refers to such a range in column 4, line 47, which is the same as the range described on page 2, lines 22-24 of the present specification, as being a shell thickness of a commonly used soft capsule.

Therefore, Iida substantially discloses that 1.00 wt% of a light-shielding agent is sufficient to impart a light-stability to a soft capsule having a commonly used shell thickness, i.e. more than 200μm to 600μm.

The examiner now recognizes the deficiency of Iida, and thus relies on Bossert, it being the examiner's position that Bossert teaches a concentration of non-water soluable light-shielding agent as great as 5%, and the examiner concludes that it would therefore have been obvious to the person of ordinary skill in the art at the time present

invention was made to abstract that teaching from Bossert and incorporate it into Iida, notwithstanding the contrary teachings of Iida. Applicants strongly disagree as explained below.

Regarding the amount of a light-shielding agent, Bossert discloses including an opacifier such as titanium oxide in gelatin capsule shell in an amount of 0.5% to 5%. However, Bossert is silent on the shell thickness of such a capsule. It is noted that Bossert is directed to an instant oral-release capsule, which can be released from the shell by the patient biting into the capsule. Please refer to column 2, lines 38-40, and lines 64-67, of Bossert. Thus, the capsule disclosed in Bossert is not swallowed by a patient, and there is no need to reduce the size of the capsule. The person of ordinary skill in the art would readily understand that Bossert suggests only a standard size of capsule, one which is relatively large and need not necessarily be swallowed.

It should be noted that the amount of 5% of opacifier disclosed in Bossert is intended to prepare a capsule having a standard wall thickness, which may be the same as the commonly used shell thickness, i.e., greater than 200μm up to 600μm, referred to in the present specification.

It is clear that neither Iida nor Bossert suggest any reduced shell thickness of a capsule or any amount of a non-water-soluble light-shielding agent higher than 5%.

Thus, a person skilled in the art would not have been motivated at the time the present invention was made, to either reduce shell thickness of capsule to 200μm or less on average, nor to include a high amount, 10 to 25 wt%, of a non-water-soluble light-shielding agent in capsule shells having such a reduced thickness.

Applicants claims are now recited as having a far greater amount of non-soluble light-shielding agent than the maximum taught by Bossert, so even if the proposed combination were obvious (respectfully denied for the reasons pointed out above), the reconstructed Iida (reconstructed in view of Bossert), would not reach the claimed subject matter.

The pending claims having the combination of the features "an average thickness of 200μm or less" and "the amount of the non-water-soluble light-shielding agent of 10 to 25 wt%" are clearly not obvious from Iida and Bossert, even if obvious combinable.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art documents not relied upon by the PTO have been noted, along with the implication that such documents are considered to be insufficiently material by the PTO to warrant their application against any of applicants' claims.

Applicants believe and submit that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration and allowance are respectfully requested.

Respectfully submitted,

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